Complete Summary

GUIDELINE TITLE

Preventing pneumococcal disease among infants and young children. Recommendations of the Advisory Committee on Immunization Practices (ACIP).

BIBLIOGRAPHIC SOURCE(S)

Advisory Committee on Immunization Practices. Preventing pneumococcal disease among infants and young children. MMWR Recomm Rep 2000 Oct 6;49(RR-9):1-38. [123 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Pneumococcal disease

GUIDELINE CATEGORY

Prevention

CLINICAL SPECIALTY

Family Practice
Infectious Diseases
Pediatrics
Preventive Medicine

INTENDED USERS

Advanced Practice Nurses
Nurses

Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide recommendations for pneumococcal vaccination in children younger than 5 years.

TARGET POPULATION

1. All children $\leq$ 23 months
2. Children aged 24-59 months with the following condition:
    - Sickle cell disease and other sickle cell hemoglobinopathies, congenital or acquired asplenia, or splenic dysfunction
    - Infection with human immunodeficiency virus (HIV)
    - Immunocompromised conditions including:
        a. Congenital immunodeficiencies: B- (humoral) or T-lymphocyte deficiency; complement deficiencies, particularly c1, c2, c3 and c4 deficiency; and phagocytic disorders excluding chronic granulomatous disease
        b. Renal failure and nephritic syndrome
        c. Diseases associated with immunosuppressive therapy or radiation therapy, including malignant neoplasms, leukemias, lymphomas, and Hodgkin's disease; or solid organ transplantation
    - Chronic illness, including:
        a. Chronic cardiac disease, particularly cyanotic congenital heart disease and cardiac failure
        b. Chronic pulmonary disease, excluding asthma unless on high dose corticosteroid therapy
        c. Cerebrospinal fluid leaks
        d. Diabetes mellitus

INTERVENTIONS AND PRACTICES CONSIDERED

1. Vaccination with 7-valent pneumococcal polysaccharide-protein conjugate vaccine (PCV7; Prevnar™ marketed by Wyeth Lederle Vaccines).
2. Vaccination with 23-valent polysaccharide vaccine (PPV23; PNU-IMUNE® 23 marketed by Wyeth-Ayerst Laboratories and Pneumovax® 23 by Merck and Company) for children aged $\geq$ 2 years who have previously received PCV7.
3. Vaccination using PCV7 for children aged $\geq$ 2 years who have previously received PPV23.

MAJOR OUTCOMES CONSIDERED

- Vaccine immunogenicity and efficacy
- Rate of invasive pneumococcal disease, including clinical pneumonia and acute otitis media
- Cost

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not applicable

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Strength of Evidence Rating Scheme

A. Strong evidence, including results of efficacy studies, supports vaccine use.
B. Moderate evidence, including immunogenicity data but not efficacy data, supports vaccine use.
C. No efficacy or immunogenicity studies are available regarding this population, but protection is anticipated on the basis of such studies among other groups; vaccination is supported by respected authorities.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Cost-Benefit Analysis

Costs and benefits of a routine PCV7 program for healthy U.S. infants and children were evaluated in a study using current estimates of pneumococcal disease burden [i.e., meningitis, bacteremia, pneumonia, and acute otitis media (AOM) episodes], clinical outcomes, vaccine efficacy, and health-care costs. Sources of clinical outcomes and costs included published and unpublished data, expert consensus, and computerized databases from Kaiser Permanente of Northern California. For each annual U.S. birth cohort, routine PCV7 vaccination is estimated to prevent approximately 12,000 (78% of potential) cases of pneumococcal meningitis and bacteremia; 53,000 (69% of potential) pneumococcal pneumonia cases; and > million (8% of potential) episodes of clinically diagnoses otitis media. Vaccination of healthy infants would result in net savings to society if vaccine costs were $\leq$ $18/dose. A program in which one dose of vaccine was administered to children aged 24-59 months to bring them up-to-date with their vaccinations would result in societal cost savings at a vaccine price of $\leq$ $80 for children aged 24-35 months and $\leq$ $50 for those aged 48-59 months. From the health-care-payer perspective, savings would result if vaccine costs were $\leq$ $40 and $\leq$ $20 when administered to children aged 24-35 months and 48-59 months, respectively, Results of this study demonstrate that cost-effectiveness of vaccination of infants and toddlers is most influenced by vaccine price, especially among children aged $\geq$ 24 months. In a recent reanalysis of cost-effectiveness of PCV7 using additional and updated information (including newly available safety data, national costs, and rates of tympanostomy tube placement), the same investigators found that break-even costs for vaccination of infants from societal and health-care payer perspective were $40 and $17, respectively.

METHOD OF GUIDELINE VALIDATION

Not stated

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not applicable

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The strength of evidence grading (A-C) is defined at the end of the "Major Recommendations" field.

Notice from the National Guideline Clearinghouse (NGC) and the Centers for Disease Control and Prevention (CDC): In February 2004, production of the 7-valent pneumococcal conjugate vaccine (PCV7), marketed as Prevnar® and manufactured by Wyeth Vaccines (Collegeville, Pennsylvania), failed to meet demand, resulting in shortages. To conserve the limited supply, CDC recommended that the fourth dose of PCV7 be withheld from healthy children. In March, because evidence indicated that production would be curtailed for several months, CDC recommended that the third dose also be withheld. As of July 2004, production problems appear to have been resolved. As a result, deliveries are projected to permit the recommendation that every child receive 3 doses. Some providers might have short-term difficulties obtaining vaccine because of

distribution delays; however, every effort will be made to provide sufficient vaccine to all providers. For more information, refer to the CDC Web site.

Children for Whom 7-valent Pneumococcal Polysaccharide-Protein Conjugate Vaccine (PCV7) Is Recommended

Children Aged <23 Months

All children aged ≤23 months should be vaccinated with PCV7 (see Table 8 of the original guideline document). Infant vaccination provides the earliest possible protection, and children aged ≤23 months have the highest rates of pneumococcal infection. PCV7 is safe and highly efficacious in preventing invasive disease, and it is effective in preventing a portion of acute otitis media cases and pneumonia among healthy infants and young children (Strength of evidence: Children aged 2-6 months, A; children aged 7-23 months, B – see Table 9 of the original guideline document)

Vaccination Schedule. Infants receiving their first dose at age ≤6 months should receive three doses of PCV7 at intervals of approximately 2 months, followed by a fourth dose at age 12-15 months. Newborns should begin the schedule at age 2 months, although PCV7 can be administered as young as age 6 weeks. Prematurely born infants (i.e., <37 weeks gestation) should receive PCV7 at the recommended chronologic age concurrent with other routine vaccinations. For infants with prolonged nursery stays, initiation of vaccination should begin during discharge planning. Children aged ≥7 months not previously vaccinated should also be vaccinated according to the recommended schedule (see Table 10 of the original guideline document). The proposed vaccination schedule is the same for all children aged ≤23 months, regardless of the presence of underlying medical conditions (e.g., children with HIV infection, sickle cell disease or other asplenia, chronic disease, or who are otherwise immunocompromised). Interruption of the vaccination schedule does not require reinstitution of the entire series or the addition of extra doses (see Table 11 of the original guideline document).

Children Aged 24-59 Months Who Are at High Risk for Pneumococcal Infection

Children aged 24-59 months should receive PCV7 vaccination if they are at high risk for pneumococcal infection caused by an underlying medical condition. This recommendation applies to the following groups:

- children with sickle cell disease and other sickle cell hemoglobinopathies, including hemoglobin SS, hemoglobin S-C, or hemoglobin S-beta-thalassemia, or children who are functionally or anatomically asplenic;
- children with HIV infection;
- children who have chronic disease, including chronic cardiac and pulmonary disease (excluding asthma), diabetes mellitus, or cerebral spinal fluid leak; and
- children with immunocompromising conditions, including (a) malignancies (e.g., leukemia, lymphoma, Hodgkin's disease); (b) chronic renal failure or nephrotic syndrome; (c) those children receiving immunosuppressive chemotherapy, including long-term systemic corticosteroids; and (d) those children who have received a solid organ transplant.*

*Note: This recommendation excludes children who have received a bone marrow transplant (BMT). Children who undergo bone marrow transplantation have impaired humoral immune system responses for months or years after the procedure and are at increased risk for serious pneumococcal infection. Because studies among this population are not complete, the Advisory Committee on Immunization Practices is currently unable to make recommendations regarding use of PCV7 among bone marrow transplant patients. PCV7 might produce superior antibody responses compared with 23-valent polysaccharide vaccine (PPV23) among bone marrow transplant patients. However, pending results of studies of PCV7 among bone marrow transplant patients, health-care providers should vaccinate this population with PPV23 vaccine at 12 and 24 months after bone marrow transplant, as recommended by an expert panel (Guidelines for preventing opportunistic infections among hematopoietic stem cell transplant recipients. Recommendations of the Centers for Disease Control and Prevention [CDC], the Infectious Disease Society of America, and the American Society of Blood and Marrow Transplantation. MMWR Morb Mortal Wkly Rep 2000 Oct 20;49[RR-10]:1-125).

Immunogenicity and safety studies have been conducted using PCV7 among children with sickle cell disease and a 5-valent conjugate vaccine among children with HIV infection [Vernacchio et al., 1998; O'Brien et al., 1996; Nowak-Wegrzyn et al., 1999 (Strength of evidence: B)]. The efficacy of PCV7 among children with chronic disease or who are immunocompromised has not been evaluated, but effectiveness is anticipated on the basis of studies conducted in other groups [King et al., 1996; King et al., 1997 (Strength of evidence: C)].

Vaccination Schedule. For children aged 24-59 months with underlying medical conditions (see Table 8 of the original guideline document), the Advisory Committee on Immunization Practices recommends two doses of PCV7, administered 2 months apart, followed by one dose of PPV23 administered $\geq$2 months after the second dose of PCV7 (see Tables 10 and 12 of the original guideline document). The recommendation for two PCV7 doses is based on results of an immunogenicity study conducted among sickle cell disease patients. That study reported that a nonstatistically significant antibody response to serotype 6B after one dose of PCV7 increased statistically significantly after a second dose of PCV7 (Vernacchio et al., 1998). Serotype 6B is one of the most common pneumococcal serotypes colonizing or causing invasive disease among sickle cell disease patients and healthy children.

Penicillin prophylaxis should be continued for children with sickle cell disease to age >5 years, regardless of vaccination with PCV7. Protective efficacy of PCV7 for children with sickle cell disease has not been studied, and the vaccine does not protect against all serotypes causing disease. However, penicillin prophylaxis substantially reduces the risk for invasive pneumococcal infections among sickle cell disease patients (Gaston et al., 1986).

Other Children Who Might Benefit from Vaccination with PCV7

The Advisory Committee on Immunization Practices recommends that health-care providers consider PCV7 vaccination for all other children aged 24-59 months, with priority given to the following populations:

- children aged 24-35 months
- children of Alaska Native or American Indian descent
- children of African-American descent
- children who attend group day care centers*

*Note: A "day care center" is defined here as any setting outside the home where a child regularly spends ≥4 hours/week with ≥2 unrelated children under adult supervision.

This recommendation is made on the basis of the moderate risk for pneumococcal disease, including antibiotic-resistant infections, among these populations and on potential cost-benefit. Data regarding efficacy and immunogenicity of PCV7 are limited for these specific risk and age groups. However, the vaccine is safe and immunogenic among all healthy children aged 24-59 months. Also, immunogenicity data are available regarding use of another pneumococcal conjugate vaccine among Apache, Navajo, and Alaska Native children (Miernyk et al., 2000), and efficacy data for children aged ≤23 months probably are relevant for healthy children aged 24-59 months (Strength of Evidence: B).

PPV23 is licensed for use among children aged ≥2 years who are at high risk for pneumococcal infections (e.g., those with sickle cell disease or HIV infection). However, the conjugate vaccine has advantages over PPV23, which include induction of immune system memory (possibly resulting in longer duration of protection), reduction in carriage, probable higher efficacy against serotypes causing most invasive disease, and probable effectiveness against noninvasive syndromes (e.g., nonbacteremic pneumonia and acute otitis media). If pneumococcal vaccine is to be used among healthy children aged 24-59 months, the Advisory Committee on Immunization Practices recommends that PCV7 be used.

Vaccination Schedules. The Advisory Committee on Immunization Practices recommends that one dose of PCV7 be considered for Alaska Native and American Indian children aged 24-59 months. Previously, the Advisory Committee on Immunization Practices recommended PPV23 for Alaska Natives and certain American Indian populations aged ≥2 years. However, use of PCV7 among these children offers multiple potential advantages over PPV23 as previously discussed. In contrast, PPV23 offers potentially broader serotype coverage. Recent studies demonstrate that only 68% and 57% of invasive infections among Alaska Natives and American Indians in the U.S. Southwest aged 24-59 months, respectively, were caused by serotypes included in the 7-valent conjugate vaccine, lower proportions than among non-Alaska Native/non-American Indian populations. Therefore, vaccination program personnel and other health-care providers might consider whether Alaska Native and American Indian children aged 24-59 months would benefit by the additional coverage provided by the 23-valent polysaccharide vaccine. Data are limited regarding safety and immunogenicity of PPV23 after PCV7. If additional serotype coverage is desired by parents and health-care providers, PPV23 should be administered ≥2 months after PCV7 (Strength of evidence: C). A community-randomized trial to evaluate the efficacy of PCV7 among Navajo and Apache children in preventing pneumococcal disease is underway. Future recommendations for use of PCV7 among Alaska Native and American Indian populations might be modified on the basis of that trial.

The Advisory Committee on Immunization Practices recommends that physicians consider administering one dose of PCV7 to their African-American pediatric patients aged 24-59 months because of their increased risk for pneumococcal infection. The proportion of invasive pneumococcal disease among African-American children that is caused by PCV7 serotypes does not differ from whites in the United States, and rates of invasive disease decline with age. Therefore, no additional vaccination with PPV23 is recommended (Strength of evidence: B). Additionally, because of increased risk for invasive pneumococcal disease, colonization with antibiotic-resistant pneumococcal strains, and acute otitis media, health-care providers should consider administering one dose of PCV7 to previously unvaccinated children aged 24-59 months who attend group day care centers.

Children Aged ≥5 Years and Adults Who Are At High Risk for Pneumococcal Infection

Data are limited regarding efficacy of PCV7 among children aged ≥5 years and adults. However, limited studies report that (a) 5-valent pneumococcal conjugate vaccine is immunogenic among HIV-infected children aged 2-9 years; (b) PCV7 is immunogenic among children aged 2-13 years with recurrent respiratory infections; and (c) PCV7 is immunogenic among older children and adults aged 4-30 years with sickle cell disease. Administering PCV7 to older children with high-risk conditions is not contraindicated.

Studies among healthy adults aged ≥50 years and among HIV-infected adults aged 18-65 years did not demonstrate substantially greater enzyme-linked immunosorbant assay (ELISA) antibody concentrations after administration of 5-valent pneumococcal conjugate vaccine compared with PPV23. Also, the proportion of invasive pneumococcal isolates covered by PCV7 is only 50%-60% among older children and adults, in contrast with 80%-90% coverage by PPV23 among this older group. Therefore, current data do not support a recommendation to replace PPV23 with PCV7 among older children and adults.

Recommendations for Use of PCV7 Among Children Previously Vaccinated with PPV23

Children aged 24-59 months who are at high risk for pneumococcal disease and who have already received PPV23 (i.e., children with sickle cell disease, HIV infection, or who have other immunocompromising illnesses or chronic diseases) could benefit from the immunologic priming and T-cell-dependent immune system response induced by PCV7. Thus, among children in these groups at high risk, sequential use of the two pneumococcal vaccines can provide additional protection. Health-care providers should vaccinate children aged 24-59 months at high risk who have not previously received PCV7 but who have already received PPV23 with two doses of PCV7 administered ≥2 months apart. Vaccination with PCV7 should be initiated ≥2 months after vaccination with PPV23. Providers should be aware that minimal safety data are available regarding this vaccine sequence.

Recommendations for Use of PPV23 Among Children Previously Vaccinated with PCV7

Administration of PCV7 Followed by PPV23 Among Children at High Risk for Pneumococcal Disease

Children who have completed the PCV7 vaccination series before age 2 years and who are among risk groups for which PPV23 is already recommended should receive one dose of PPV23 at age 2 years (≥2 months after the last dose of PCV7). These groups at high risk include children with sickle cell disease, children with functional or anatomic asplenia, children who are HIV-infected, and children who have immunocompromising or chronic diseases (CDC, 1997) (see Table 8 of the original guideline document). Although data regarding safety of PPV23 administered after PCV7 are limited, the opportunity to provide additional serotype coverage among these children at very high risk justifies use of the vaccines sequentially. For children of Alaska Native or American Indian descent, addition of PPV23 after PCV7 can be considered.

Revaccination with PPV23

Immunocompromised children or children with sickle cell disease or functional or anatomic asplenia should be revaccinated with PPV23 as previously recommended (CDC, 1997) (see Table 12 of the original guideline document). If the child is aged ≤10 years, one revaccination should be considered 3-5 years after the previous dose of PPV23 (CDC, 1997; American Academy of Pediatrics, 2000). Data are limited regarding adverse events related to a second dose of PPV23 administered after PCV7. Health-care providers should not administer a second dose of PPV23 any earlier than 3 years after the initial dose of PPV23.

Strength of Evidence Rating Scheme

A. Strong evidence, including results of efficacy studies, supports vaccine use.
B. Moderate evidence, including immunogenicity data but not efficacy data, supports vaccine use.
C. No efficacy or immunogenicity studies are available regarding this population, but protection is anticipated on the basis of such studies among other groups; vaccination is supported by respected authorities.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for selected recommendations (see â œMajor Recommendationsâ).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Prevention of invasive pneumococcal disease in healthy children

  At the time of the primary efficacy analysis conducted in August 1998, 7-valent pneumococcal polysaccharide-protein conjugate vaccine (PCV7) was 100% efficacious against vaccine serotypes among children who were either fully vaccinated or partially vaccinated.

- Prevention of pneumonia of any etiology

  Among children who received $\geq$1 doses of study vaccine, use of PCV7 resulted in 11.4% fewer episodes of clinical pneumonia, regardless of x-ray or culture result. Cases of clinical pneumonia accompanied by an x-ray with any evidence of an infiltrate were reduced by 33.0%. Among children who had clinically diagnosed pneumonia and x-ray evidence of an area of consolidation of $\geq$2.5 cm as read by both a pediatrician and a radiologist, efficacy of PCV7 was 73.1%.

- Prevention of health care visits for acute otitis media

  Compared with children who received control vaccine, children who received PCV7 had 6.4% fewer episodes of acute otitis media, 9.1% fewer episodes of frequent acute otitis media, and they underwent 20.3% fewer tympanostomy tube placements.

- Prevention of acute otitis media

  A total of 107 episodes occurred among the PCV7 group, and 250 among the control group, for an estimated efficacy of 57% against culture-confirmed acute otitis media caused by vaccine serotypes.

- Decreased use of antibiotics

  The Northern California Kaiser Permanente vaccine efficacy trial (Black S. Implementation of pneumococcal and meningococcal conjugate vaccines [Presentation]. Pediatric Academic Societies and the American Academy of Pediatrics Joint Meeting, Boston, MA, 2000) reported a 5.3% reduction among the group of children who received PCV7.

Subgroups Most Likely to Benefit:

Children who are at high risk for pneumococcal infection

- Children with sickle cell disease and other sickle cell hemoglobinopathies, including hemoglobin SS, hemoglobin S-C, or hemoglobin S-beta-thalassemia, or children who are functionally or anatomically asplenic;
- Children with HIV infection;

- Children who have chronic disease, including chronic cardiac and pulmonary disease (excluding asthma), diabetes mellitus, or cerebral spinal fluid leak; and
- Children with immunocompromising conditions, including (a) malignancies (e.g., leukemia, lymphoma, Hodgkin's disease); (b) chronic renal failure or nephrotic syndrome; (c) those children receiving immunosuppressive chemotherapy, including long-term systemic corticosteroids; and (d) those children who have received a solid organ transplant.

POTENTIAL HARMS

- Fever >100.4 F(>38 degrees C) less than 48 hours after vaccination was more common among children who received 7-valent pneumococcal polysaccharide-protein conjugate vaccine (PCV7) concomitantly with diphtheria, tetanus and acellular pertussis (DTaP) vaccine and other recommended vaccines than among those who received the control vaccine.
- Febrile seizures after vaccination were slightly more common in the PCV7 group; however, the majority of events occurred when whole-cell pertussis vaccine was administered concurrently with PCV7.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Advisory Committee on Immunization Practices. Preventing pneumococcal disease among infants and young children. MMWR Recomm Rep 2000 Oct 6;49(RR-9):1-38. [123 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 Oct. 6

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Advisory Committee on Immunization Practices (ACIP)

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

An update is not in progress at this time.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site.

Also available (in Portable Document Format [PDF]) from the Centers for Disease Control and Prevention (CDC) Web site.

Print copies: Available from CDC, MMWR MS (C-08), Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 20, 2000.

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